REMARKS

Claims 21-23 are pending in this continuation application. No claims have been cancelled. No claims have been added. Claim 21 has been amended.

Claims 21-23 have been rejected under 35 U.S.C § 112, first paragraph, as being non-enabled by the specification. It is the Examiner's view that the specification is enbabling for only reducing the risk of cervical dysplasia or cervical carcinoma in a subject, not for treating or preventing these disorders. In particular, the Examiner objects subparagraph (iii) of claim 21. As noted in the previous Response to Office Action, applicants do not agree with the Examiner's view regarding this issue. However, in an effort to move prosecution along in this case the claims have been amended, as set forth above, to address the rejection issued under § 112. In view of these claim amendments, applicants believe that the rejection has been traversed.

Claims 21-23 have been rejected under 35 U.S.C § 103(a) over Wood et al. in view of Jackson '011, further in view of Bamji et al and US Patent No. 5,254,572. With respect to Wood et al and Jackson, the Examiner relies on the same arguments advanced in the previous Office Action in support of this rejection. Applicants request that this rejection be withdrawn since these references do not teach or even suggest the claimed method.

Wood merely restates what is already known in the art, i.e., the use of oral contraceptives can interfere with folic acid absorption and/or metabolism of folic acid. (See also, the instant specification at page 3, lines 18-25). Jackson '011 also reiterates what is known in the art, namely, that women with decreased levels of folic acid are subject to increased risks for conditions such as cervical dysplasia and cervical cancer. This is also discussed in the instant specification.

Bamji suggests that intermittent vitamin supplementation can be achieved by including vitamins in the seven non-hormone tablets in each contraceptive pill package. The reference does not teach or suggest daily administration of folic acid by combining folic acid with an oral contraceptive in the same dosage unit. Thus, Bamji fails to provide a method of administering folic acid that provides an adequate level of folic acid for those women who accidentally become pregnant while taking oral contraceptives. The '572 patent likewise fails to teach or suggest a method for the chronic, daily administration of

folic acid. The '572 patent is concerned with administration of B6 vitamins and suggests that these vitamins can be included in oral contraceptive tables. The reference shows no appreciation of the risks of cervical dysplasia and cervical carcinoma for women who accidentally become pregnant while taking oral contraceptives, or the present method of reducing those risks by combining folic acid and oral contraceptives to provide for chronic, daily folic acid administration.

Only through applicants' own teachings could one skilled in the art be led to the claimed method, wherein folic acid is administered in combination with an oral contraceptive to insure that women using oral contraceptives maintain regular and sufficient folic acid supplementation. Such hindsight reconstruction of the prior art using applicants' own teachings is clearly impermissible.

The Examiner cites In re Fine, 5 USPQ 2d 1596 (Fed. Cir. 1988) and In re Jones, 21 USPQ 2d 1941 (Fed. Cir. 1992) in support of the proposition that the rational for combining or modifying the prior art need not be expressly stated in the art. According to the Examiner's reading of these cases, it is sufficient for the rational to be either expressly or impliedly contained in the prior art or that the rational may be reasoned from knowledge generally available to those skilled in the art, established by general principles, or legal precedent.

A fair reading of these cases does not permit the PTO such broad leeway in establishing the rational for combining references. The rational for combining or modifying the art is limited to an objective teaching in the art or to an adequate suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In both Fine and Jones the Court found that the PTO had failed to provide proper motivation for combining the references at issue because there was no such objective teaching or adequate suggestion. This is precisely the situation in the present case. None of the cited references, either alone or in combination, suggests any appreciation for the risks of cervical dysplasia and cervical carcinoma in women who are taking oral contraceptives. Such an appreciation would require recognition of the fact that such women can accidentally become pregnant while taking contraceptives and that if this occurs they may very well have insufficient levels of folic acid to reduce the risks of contracting the specified disorders.

There is simply no adequate motivation found in the cited references to support combining them in the manner advocated by the Examiner.

In view of the foregoing, applicants believe that claims 21-23 are in condition for allowance and a Notice of Allowance directed to these claims is requested at the earliest possible date.

Applicants hereby petition for a one-month extension of time in order to respond to the outstanding Office Action. Please charge the fee of $120.00 required under 27 C.F.R. § 1.17 (a)(1), and any additional fees that may be required to Deposit Account No. 10-0750/ORT-1316/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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